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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,708	10/03/2003	Charlotte A. Kensil	8449-322-999	9606
20583	7590	10/21/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,708	KENSIL ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-59 and 61-68 is/are pending in the application.
- 4a) Of the above claim(s) 54,55,58,59,61,62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-53,56,57,63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Claims 46-59 and 61-68 are pending.

Claims 46, 54, 55, 63 and 65 have been amended.

Claims 54, 55, 58, 59, 61 and 62 are withdrawn from further consideration by the examiner 37 CFR 1.142(b) as being drawn to a nonelected species.

Claims 46-53, 56, 57 and 63-68 drawn to a method for enhancing immune response with a composition comprising an antigen, wherein the antigen is a protein, saponin adjuvant, and an excipient, wherein the excipient is a polysorbate are under consideration in the instant application (Restriction Requirement on 10/21/04 and Office Action on 1/11/05)

3. Applicant's Remark filed on 9/13/05 been entered. In view of Applicants' arguments, the rejection of record under 35 U.S.C. 103 has been withdrawn.

4. The following new ground of rejections is necessitated by applicant's amendment and addition of new claims filed on 9/13/05.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 46, 49-53, 56, 57 and 63-68 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6, 146, 632.

The '632 patent teaches an immunogenic composition comprising antigen (i.e. polypeptide, glycoprotein or lipoprotein from bacterial or viral sources col. 3, lines 46-65), QS-21 in an oil-in water emulsion comprising TWEEN 80 (polysorbate, polyoxyethylene sorbitan monooleate 80) (col. 1, lines 3-40, col. 3, lines 26-38, Examples 1-2, claims 1-8). The '632 patent teaches a QS-21 and/or 3-De-O-acylated monophospholipid A (3D-MPL) in oil-in water composition comprising TWEEN (col. 1, lines 8-13). Even if the '632 patent teaches additional adjuvant (3D-MPL), it is well known in the art a combination of different adjuvants to achieve wide spectrum of immune responses (i.e. CTL, Th-1 or Th-2), the '632 patent clearly teaches the combination of QS-21 and TWEEN 80.

The '632 patent further teaches the use of the composition to enhance immune response and administration to human (Examples 1-2, col. 4, lines 31-36).

Claim 53 is included as QS-7 saponin fragment being a by-product of QS-21 purification by the reference incorporated by both reference and claimed invention, U.S. Pat. 5, 057,540. Thus, the reference teachings anticipate the claimed invention.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,146,632 in view of U.S. Pat. No. 5,057,540.

The '632 patent has been discussed, *supra*.

The '632 patent does not teach heterogeneous Quil-A saponin.

However, the '540 patent teaches Quil-A is readily available in "mg" quantity and shows a good adjuvant activity (col. 4, lines 22-26, col. 10, lines 43-48).

Therefore, one of the ordinary skill in the art would have been motivated to combine the readily available Quil-A and teachings by the '632 patent because the Quil-A saponin would have adjuvant effect and more available in larger quantities.


From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
October 11, 2005


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